Supreme Court, U.S.
FILED
NOV 14 20
OFFICE OF THE CLERK

(2)

No. 01-441

In the Supreme Court of the United States

BILLYE JEAN MARTIN AND LIRBA SALAZAR,

Petitioners,

v.

MEDTRONIC, INC.,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF FOR THE RESPONDENT IN OPPOSITION

RUTH G. MALINAS
Ball & Weed, P.C.
745 E. Mulberry, Ste. 500
San Antonio, Texas 78212
(210) 731-6300

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

Counsel for Respondent

36pp

QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state-law claims challenging the design of Medtronic's Model 4004 and Model 4004M pacemaker leads, the manufacturing processes used to make the devices, and the devices' labeling, where those devices were granted pre-market approval by the Food and Drug Administration ("FDA"), and where each of petitioners' claims would impose requirements relating to the safety or effectiveness of the devices that would be "different from, or in addition to" the federal requirements embodied in the FDA's pre-market approval of those devices.

RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

TABLE OF CONTENTS

	Page
QUESTION PRESENTED	I
RULE 29.6 STATEMENT	ii
TABLE OF AUTHORITIES	iv
STATEMENT	1
A. The Regulatory Structure Of The Medical Device Amendments.	2
B. The Extensive Regulatory History Of The Model 4004 and 4004M Devices.	4
C. Petitioners' Cases In The Lower Courts	10
REASONS FOR DENYING THE PETITION	14
I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR.*	15
A. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption Of State Law Tort Actions	15
B. While There Is Some Inconsistency In The Lower Courts, It Is Far More Limited Than Petitioners Assert	16
II. THE DECISION BELOW, FINDING PREEMPTION OF STATE LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT	22
CONCLUSION	27

TABLE OF AUTHORITIES

Page(s)

CASES

Brooks v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (2001) 16, 18, 20

Buckman Co. v. *Plaintiffs' Legal Comm.*, 121 S. Ct. 1012 (2001) ..... *passim*

Connelly v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) 19

Fry v. *Allergan Med. Optics*, 695 A.2d 511 (R.I. 1997) 18, 20

Goodlin v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) 18

Green v. *Dolsky*, 685 A.2d 110 (Pa. 1996) 18, 20

Kemp v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001) ..... *passim*

Medtronic, Inc. v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*

Mitchell v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) 18, 20, 23

Niehoff v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997) 19, 21

Oja v. *Howmedica, Inc.*, 111 F.3d 782 (1997) 20, 21

Papike v. *Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997) 20

Smith Indus. Med. Sys., Inc. v. *Kernats*, 522 U.S. 1044 (1998) (mem.) 27

Stamps v. *Collagen Corp.*, 984 F.2d 1416 (1993) 12, 13

TABLE OF AUTHORITIES – continued

Page(s)

Uniroyal Goodrich Tire Co. v. *Martinez*, 977 S.W.2d 328 (Tex. 1998) 25

Weiland v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999) 18, 19

Worthy v. *Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) 18, 20

STATUTES, RULES AND REGULATIONS

Food Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* 1

Medical Device Amendments, 21 U.S.C. § 360c *et seq.* ..... *passim*

21 U.S.C. § 331 22

21 U.S.C. § 351 22

21 U.S.C. § 360 ..... 22, 23

21 U.S.C. § 360c 2, 8, 23

21 U.S.C. § 360e 3, 8, 23

21 U.S.C. § 360j 23

21 U.S.C. § 360k ..... *passim*

21 U.S.C. § 382 23

21 C.F.R. § 808.1 ..... 21, 24

21 C.F.R. § 814.20 6

21 C.F.R. § 814.39 23

21 C.F.R. § 814.80 23

21 C.F.R. Pt. 820 8

TABLE OF AUTHORITIES – continued

Page(s)

21 C.F.R. § 820.01 8

21 C.F.R. § 860.7 26

S. Ct. R. 10 20

MISCELLANEOUS

3 COMM. ON PATTERN JURY CHARGES, STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES PJC 71.4B (1998) 26

FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce, 97th Cong., 2d Sess. 5 (1982) 26

Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) 24

Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321 (Oct. 10, 1980) 19

H.R. REP. NO. 94-853 (1976) 2, 24, 26, 27

Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977) 17

TEX. CIV. PRAC. & REM. CODE § 82.005 (Vernon 1997) 25

United States Brief in *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 121 S. Ct. 1012 (2001) 27

TABLE OF AUTHORITIES – continued

Page(s)

United States Brief in *Smith Indus. Med. Sys., Inc.* v. *Kernats*, 522 U.S. 1044 (1998) (mem.)..... 27

BRIEF FOR THE RESPONDENT IN OPPOSITION

The petition for certiorari in this case is virtually identical to that filed in *Kemp* v. *Medtronic, Inc.*, No. 00-1766, which this Court denied on October 1, 2001. See 122 S. Ct. 48. There is no reason for a different disposition of the present petition. The petitioners in both cases assert that the Court should grant review because *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), has caused confusion in the lower courts. However, like *Kemp*, the instant case — which was decided by the Fifth Circuit consistently with both *Lohr* and the holdings of the great majority of lower courts — is not the vehicle in which to attempt to clarify the scope of preemption under Section 360k of the Medical Device Amendments (MDA), 21 U.S.C. § 360c *et seq.*, to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*

While there may be some inconsistency in lower courts' interpretations of *Lohr*, the conflict in authority is not nearly as "deep" or "profound" as petitioners contend. The overwhelming weight of authority supports the Fifth Circuit's view that the FDA's rigorous pre-market approval (PMA) process, which is vastly different from the "substantial equivalence" review given the device at issue in *Lohr*, yields federal requirements that are specific to the device and preemptive under the *Lohr* framework. Furthermore, this Court's recent decision in *Buckman Co.* v. *Plaintiffs' Legal Committee*, 121 S. Ct. 1012 (2001), may very well influence how lower courts analyze and ultimately determine the preemptive effect of the PMA process. Giving the lower courts the opportunity to address these issues in light of *Buckman* could preclude any need for this Court's intervention.

STATEMENT

As in *Kemp*, the petition provides almost no information about either the claims that petitioners actually raised below or about the lengthy and comprehensive PMA process to

which the specific medical devices at issue were subjected. After briefly outlining the background legal structure applicable to preemption under the MDA, we set forth these critical facts.

A. The Regulatory Structure Of The Medical Device Amendments.

In 1976, Congress enacted the MDA, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no State may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA — in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class III" devices (those that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)), if those devices had been approved for sale through a simple "pre-market notification" under the "510(k)" process as the

"substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492-493.

The *Lohr* Court explicitly differentiated 510(k) approval of a device from the PMA process, at issue in this case:

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

518 U.S. at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review, *id.* at 479, and never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held that one needed to engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that were arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504-505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506-507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process — which focuses on "entirely ge-

neric concerns about device regulation generally" (*id.* at 501), that is, on the competitive disadvantage that would be caused if new items the substantial equivalent of a pre-existing device were not easily marketable — did not pre-empt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption where a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device, and thus plaintiffs would not have been injured. The Court — noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (121 S. Ct. at 1020) — found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 1019.

B. The Extensive Regulatory History Of The Model 4004 and 4004M Devices.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 121 S. Ct. at 1015; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. The path to approval of the Models 4004 and 4004M pacemaker leads at issue in this case demonstrates the thoroughness of that review.[1] When the FDA approved Medtronic's

---

[1] Petitioner Martin received a Model 4004 pacemaker lead, while Petitioner Salazar received a Model 4004M lead. As explained further below (at 9), the Model 4004 was the immediate predecessor to the Model 4004M; the only difference between the two is a

application for pre-market approval of the Model 4004M, on March 28, 1990, that approval was the culmination of a rigorous administrative process that began *eight years* earlier, with Medtronic's 1982 application for an investigational device exemption ("IDE") to permit clinical trials of the predecessor, Model 4003 lead. Before the FDA determined, in approving the Model 4004M and 4004 PMAs, that Medtronic had proffered valid scientific evidence providing a reasonable assurance that those leads were safe and effective for their intended use, the devices and their direct predecessor models (in particular, the Model 4003) were rigorously reviewed and critically evaluated for safety and efficacy by the FDA, in light of the known and potential complications that could arise from their use, on numerous occasions between 1982 and 1990.

The following is a brief chronology of the FDA's review leading up to its approval of the Model 4004 and Model 4004M pacemaker leads.[2]

- Medtronic filed its initial IDE application for the Model 4003 lead on March 26, 1982.

---

minor change to a connector pin. Both devices were subjected to similar agency review — the successor 4004M lead was approved through a "PMA supplement" to the 4004 lead approval. See page 9-10, *infra*. Petitioners have never contended that there is any significant difference between the 4004 and 4004M leads; in fact, in their brief to the Fifth Circuit they incorrectly asserted that both petitioners received Model 4004M leads, while in this Court they incorrectly assert (at Pet. 10) that both petitioners received Model 4004 leads.

[2] This description is based on the affidavit of Charles H. Swanson at Salazar R.1520-40, and the affidavit of Charles H. Swanson at J.A. 98-119 in *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000), *cert. denied*, 122 S. Ct. 48 (2001); see also *id.* at 219; Salazar R. 888-894; Martin R. 805-811, 1661-1679.

- That application was denied by the FDA, in a letter dated May 6, 1982, pending submission of more detailed information regarding Medtronic's proposed clinical trial.

- Medtronic provided the requested information, and the FDA approved the IDE for the Model 4003 on June 28, 1982. The FDA prohibited any significant change in the investigation without advance FDA approval, however.

- Medtronic later requested authority to expand the clinical trial. In a June 29, 1983 letter, the FDA denied Medtronic's request, and required it to continue the investigation under the existing limits.

- Medtronic filed its PMA application for the Model 4003 lead on September 30, 1983. The application contained all of the detailed product and labeling information required by 21 C.F.R. §§ 814.20 *et seq*.

- FDA staff reviewed the Model 4003 PMA application, and by letter of November 29, 1983 required Medtronic to submit additional information concerning (1) the animal and *in vitro* testing of the lead so that FDA reviewers could better evaluate the testing, and (2) "the fate of the implanted lead, in terms of potential long term degradation of the insulating materials."

- Medtronic responded on February 14, 1984, providing detailed descriptions of completed testing as well as a compilation of published scientific literature and other relevant documents.

- On April 23, 1984, the FDA approved additional implants in the clinical trial, "for the purpose of determining whether or not to file a PMA," but required those implants to be performed by physicians who

had particular experience recognizing potential complications from the leads.

- By letter of July 30, 1984, the FDA required Medtronic to supply additional information for its PMA review.
- Medtronic filed annual reports about the IDE trials of the 4003 lead yearly between 1983 and 1986.
- The FDA requested additional information about lead survival experience in the IDE investigation after receiving Medtronic's 1984 IDE annual report.
- In September 1985, Medtronic filed a supplement to the IDE, seeking FDA approval to permit fundamental design changes to be made in the lead and to revise the reporting requirements concerning field performance of the lead.
- Also in September 1985, Medtronic filed an amendment to its PMA application in response to the FDA's July 30, 1984 letter. Medtronic furnished extensive data regarding the performance of prior lead models through its chronic lead performance database and through information gleaned from returned product analyses.
- The FDA approved the supplemental IDE in October 1985.
- The FDA demanded additional test and clinical data regarding the Model 4003 as a part of the PMA review in December 1985, and required amendments to the proposed warranty language.
- Medtronic responded in March 1986 by filing another supplemental PMA that explained in greater detail technical aspects of the lead's design, compared those with prior lead models, and analyzed data on the performance of those prior lead models. In addition,

Medtronic provided an analysis of data generated from the clinical trials of the 4003 lead.

- In April 1986 — 30 months after Medtronic first filed a PMA request — the FDA advised Medtronic that the Model 4003 PMA was "suitable for filing," and would undergo the scientific and compliance review provided for in 21 U.S.C. §§ 360c, 360e(c)(2). The FDA also advised Medtronic that it would have to demonstrate that its facilities complied with all applicable "Good Manufacturing Practice" (GMP) rules and regulations under 21 C.F.R. Pt. 820.

- On May 23, 1986, the FDA referred the Model 4003 application to a panel of independent scientists for review. The panel concluded that Medtronic had submitted "valid scientific evidence" sufficient to be used to evaluate the safety and effectiveness of the Model 4003 lead. The panel members concluded that the information provided reasonable assurance that the device was safe and effective for its intended use, and that the reports of complications and adverse reactions did not outweigh the benefits from use of the device.

- Based upon the record before it, the FDA approved the PMA application for the Model 4003 lead on July 29, 1986.

- The FDA formally acknowledged the closure of the IDE investigation for the Model 4003 lead in April 1987.

- On July 15, 1988, Medtronic filed a PMA application for the Model 4004 lead, as a supplement to the PMA for the Model 4003. The new application again complied in full with the requirements of 21 C.F.R. § 820.01 *et seq.* in both content and detail. In addition to providing extensive information on the new

product's configuration, *in vitro* and *in vivo* testing of electrical performance, biostability test data, clinical test data about a prototype model tested in Canada, and copies of all proposed labels and warranty documents, Medtronic provided details of a newly-developed biostability test that replicated in a laboratory setting an insulation failure mode experienced in prior lead models. Appendices contained extensive data on lead survivability, both from Medtronic's "Chronic Lead Study" and from the analysis of prior lead models returned from the field.

- In response to this application, the FDA required Medtronic to modify the labeling of the Model 4004 to state explicitly that clinical trials had only been done on a unipolar version of the lead. Medtronic complied by submitting a revised label to the agency.

- The FDA approved the Model 4004 PMA Supplement on February 10, 1989, judging that Medtronic had provided valid scientific evidence upon which it could conclude that the device was safe and effective for its intended use. The FDA required, as a condition of approval of the Model 4004 PMA, that a further PMA Supplement be filed before any change was made to the device that could affect its safety or effectiveness. In addition, the FDA required Medtronic to continue to report, post-approval, on the performance of the lead.

- Medtronic filed another PMA Supplement, seeking approval for the sale of the Model 4004M lead, on October 31, 1989, primarily to obtain approval to use a new type of connector pin at the end of the lead.

- The FDA approved the PMA for the Model 4004M lead on March 28, 1990, subject to the same condi-

tions of approval that governed the approval of the Model 4004 lead.

Thus, the regulatory review under the PMA process that led to the approval of the Model 4004 and 4004M leads lasted *eight years* — from March 1982 to March 1990 — and entailed detailed exchanges between the FDA and Medtronic to ensure that the agency was fully satisfied as to the testing, safety, design, and labeling of the Model 4004M lead, the Model 4004 lead, and the predecessor models to these leads.

C. Petitioners' Cases In The Lower Courts.

Lirba Salazar allegedly was injured when her Model 4004M lead malfunctioned. See Pet. App. 37a. Salazar filed a product liability action against Medtronic in the United States District Court for the Southern District of Texas on August 22, 1996.

Billye Jean Martin allegedly was injured when her Model 4004 lead malfunctioned. See Pet. App. 24a. Martin originally filed a product liability suit against Medtronic in Texas state court on August 21, 1996. Medtronic removed the case to the United States District Court for the Southern District of Texas, the same court in which Salazar's suit was pending. *Id.* at 23a.[3]

Although the complaints in both cases asserted various negligence, strict product liability and Texas Deceptive Trade Practices Act claims, including claims for negligent failure to warn, petitioners ultimately represented to the district court that they actually were bringing the following causes of ac-

---

[3] Martin and Salazar were represented by the same counsel, and both cases were before the same district court judge at the same time. Although the cases were not formally consolidated in the district court, the procedural history of and the briefing in the two cases are virtually identical. The two cases were formally consolidated on appeal.

tion: (1) claims that the leads were unreasonably dangerous as designed and manufactured; and (2) claims that Medtronic breach an implied warranty that the leads were fit and safe for their intended purposes. Pet. App. 30a-31a, 43a.

1. The District Court Proceedings.

On August 8, 1997, the district court granted in part Medtronic's motions for summary judgment in each case. The court did not find, as petitioners assert (at Pet. 11), that "*all* of petitioners' state-law claims are preempted" (emphasis added); rather, the court held that the MDA preemption provision, 21 U.S.C. § 360k(a), preempted those claims challenging the designs approved by the FDA, the manufacturing processes approved by the FDA, or the adequacy of the warnings approved by the FDA. Pet. App. 31a, 43a-44a. The district court found that such claims were preempted regardless of the theory under which they were brought. *Id.* at 31a, 44a. The court was careful to point out, however, that not all possible tort claims would be preempted, giving as an example a claim that Medtronic deviated from the manufacturing processes, specifications, or materials approved by the FDA. See *ibid.* The court gave petitioners 120 days in which to conduct discovery and decide whether to bring any non-preempted claims. Pet. App. 32a, 44a.

Petitioners chose not to pursue these non-preempted claims. Almost ten months later, Medtronic filed a second motion for summary judgment in each case, accompanied by affidavit testimony and documentary evidence establishing that Medtronic, in manufacturing the leads, had not deviated from the design, processes, specifications, or materials approved by the FDA. Petitioners did not offer any controverting evidence — neither asserting that Medtronic had intentionally altered the design or manufacturing processes of the devices without FDA approval nor asserting that petitioners' specific devices suffered from an unintentional manufacturing defect — nor did they assert any other claims they con-

tended were not preempted. Pet. App. 34a, 47a. On August 27, 1999, the district court granted Medtronic summary judgment, holding that petitioners had presented no evidence to support a claim that the leads failed to comply in any way with the FDA requirements applicable to the devices, as established through the PMA process. See *ibid.*

2. The Court Of Appeals Decision.

On appeal to the Fifth Circuit, petitioners accepted the district court's holding that in manufacturing the challenged leads Medtronic had not deviated from the processes, specifications, or materials approved by the FDA. Thus, as the Fifth Circuit observed, the only state-law claims at issue were those challenging the safety and effectiveness of the design, manufacturing processes, warnings, and labeling of the leads, as approved by the FDA. Pet. App. 3a, 21a-22a; see also Pet. 12 ("Petitioners did not pursue" any claim that Medtronic "did not use the PMA processes actually approved by the FDA.").[4]

The court of appeals began by recognizing that it was not writing on a blank slate. The Fifth Circuit had previously held, in *Stamps* v. *Collagen Corp.*, 984 F.2d 1416 (1993), "that similar state product liability claims were preempted" (Pet. App. 2a) when the device at issue had undergone the FDA's "rigorous pre-market approval procedure" (*ibid.*). To determine whether *Stamps* remained binding precedent following *Lohr*, and thus dispositive of the appeal, the court painstakingly analyzed the opinions in *Lohr*.

---

[4] In their opening brief to the Fifth Circuit (at 30-32), petitioners argued that their failure to warn claims based on information acquired after the product was approved by the FDA would not be preempted. As petitioners now acknowledge (Pet. 12), however, evidence to support such a claim was never presented.

Stamps held that common law tort suits impose state "requirements" for the purposes of MDA preemption. *Stamps*, 984 F.2d at 1423. The Fifth Circuit in this case found that a majority of the Justices in *Lohr* "clearly agreed with this proposition." Pet. App. 13a. *Stamps* also held that common law duties would be preempted "to the extent that they relate[d] to safety, effectiveness, or other MDA requirements." *Stamps*, 984 F.2d at 1424 . After carefully considering the *Lohr* majority opinion and Justice Breyer's concurrence, the Fifth Circuit concluded that *Lohr* had not overruled the *Stamps* holding "that common law tort claims challenging the safety or effectiveness of a device create specific requirements under state law." Pet. App. 18a. The Fifth Circuit further found that, "[g]iven the difference between the intensive PMA review and the minimal requirements under the Section 510(k) process," *Lohr* had not called into question *Stamps*' holding that "common law duties can impose requirements different from or in addition to the PMA process." *Ibid.*

Finally, the Fifth Circuit turned to the holding in *Stamps* that "the PMA process imposed specific federal requirements as to labeling, manufacturing, and design for the purposes of preemption." See Pet. App. 19a. Based on a detailed analysis of *Lohr*, the court of appeals determined that the FDA's express approval of the proposed design, labeling, and manufacturing of the Model 4004M lead — coupled with the statutory prohibition on modifying those requirements without FDA approval — established specific federal requirements applicable to the device under the MDA. See *id.* at 19a-21a.[5]

Recognizing that *Lohr* had held that "Congress intended the preemption of some state-law causes of action" (Pet.

---

[5] As discussed above (at 5 n.1), petitioners did not differentiate between the Model 4004 and Model 4004M leads in the court of appeals.

App. 20a), thereby triggering preemption under 21 U.S.C. § 360k(a)(1), the Fifth Circuit then turned to the specifics of petitioners' claims. As the court of appeals noted, petitioners alleged that "Medtronic breached state law duties by designing a pacemaker lead that contained certain materials, by labeling the lead with certain warnings, and by manufacturing the lead in a certain way." Pet. App. 21a. The court concluded that these claims were expressly preempted because they "relate[d] to areas specifically covered in the PMA process, and seek to impose requirements that are different from and, indeed, conflict with the PMA process." *Ibid.* Like the district court, the court of appeals found that only those claims challenging the design, manufacturing processes, and labeling *approved by the FDA during the PMA process* were preempted, but that because petitioners did not pursue any claim based on failure to abide by those FDA-approved processes, all claims presented to the court fell within this preempted category. See *id.* at 21a-22a.

REASONS FOR DENYING THE PETITION

Petitioners assert that review is necessary here because of the disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the petition, as it did only last month to the virtually identical petition filed in *Kemp*. In light of this Court's recent decision in *Buckman*, the Court should allow the lower courts time to revisit preemption issues under the MDA (see Part I.A). Moreover, as we explain in Part I.B, the lower courts are in significantly less disarray than petitioners suggest. In any event, given the extensive FDA scrutiny of the Model 4004 and Model 4004M pacemaker leads, the Fifth Circuit's decision is plainly correct (see Part II).

I. THIS CASE DOES NOT PRESENT AN APPROPRIATE VEHICLE IN WHICH TO REVISIT *MEDTRONIC, INC.* V. *LOHR.*

A. This Court Should Allow The Lower Courts To Consider The Implications Of *Buckman* For MDA Preemption Of State Law Tort Actions.

While the *Buckman* Court focused on implied preemption under the MDA, this Court should nonetheless allow the lower courts time to consider the implications of *Buckman* before expending further effort on issues that the lower courts may resolve themselves in light of that case.

At least three aspects of the *Buckman* decision may assist courts in determining the preemptive scope of the PMA process. First, the Court in *Buckman* described how "thorough" the PMA process is as compared to the 510(k) process found non-preemptive in *Lohr*. See 121 S. Ct. at 1015. Second, the Court clarified that while *Lohr* "can be read to allow *certain* state-law causes of action that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim." *Id.* at 1020 (emphasis added). Finally, the Court discussed the "somewhat delicate balance of statutory objectives" that Congress sought to achieve under the MDA scheme and stressed how allowing certain state law claims would disrupt that balance. *Id.* at 1017.

All three aspects of *Buckman* may well influence lower courts' views about the preemptive effect of the PMA process. For example, the first reinforces the accuracy of the Fifth Circuit's holding that *Lohr*'s analysis of the preemptive scope of the 510(k) process is not applicable to the PMA process. Those few courts that have found otherwise may choose to reconsider those holdings in light of *Buckman*. Indeed, the Fifth Circuit here cited *Buckman* in contrasting the 510(k) approval process with PMA review. Second, this

Court acknowledged that at least some state law claims must be preempted by the MDA; to the extent lower courts had found otherwise those courts may now conclude that they were incorrect. If, as *Buckman* held, not all state law claims that *parallel* federal requirements may proceed, 121 S. Ct. at 1020, *a fortiori* at least some of those that *differ* from federal requirement should likewise be preempted. Finally, it is hard to see how the "delicate balance" cut by the MDA would not be disrupted by allowing states to impose conflicting requirements on devices approved by the FDA pursuant to the arduous PMA process. As the dissenting judge stressed in *Brooks* v. *Howmedica, Inc.*, 236 F.3d 956 (8th Cir.), *reh'g en banc granted*, 246 F.3d 1149 (8th Cir. 2001), allowing state law failure-to-warn claims might impose "conflicting labeling requirements in various states" (*id.* at 968) that differed from the FDA's "unambiguous conclusion about how * * * competing considerations should be resolved" (*id.* at 967, quoting *Lohr*, 518 U.S. at 501).

The Eighth Circuit granted rehearing en banc in *Brooks*, where the majority had found failure-to-warn claims not to be preempted, the day after this Court decided *Buckman*. See 246 F.3d 1149. Just as that court now is reconsidering whether state law claims against manufacturers of devices approved through the PMA process are preempted, a decision it will make with *Buckman* informing its consideration, so too other courts may decide to revisit preemption in the PMA context. Thus, rather than granting review on an issue that may never require this Court's attention, this Court should deny the petition and allow further development in the lower courts.

B. While There Is Some Inconsistency In The Lower Courts, It Is Far More Limited Than Petitioners Assert.

Petitioners make a great deal about the "deep post-*Lohr* split in authority" — as did petitioners in *Kemp* — asserting

that there is a conflict "in two important and related respects." Pet. 14. Their first issue, however — "whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims" (*ibid.*) — is in fact nothing but a confused summary of one aspect of their second issue. That second issue in turn has two parts; petitioners assert that there are conflicts both on whether the PMA process imposes specific, federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. While a few courts have misinterpreted *Lohr* on both what federal requirements may be preemptive and on whether state common law claims may be preempted, the great weight of authority — and all recent authority — favors the Fifth Circuit's position on both issues.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to the device are preemptive under the MDA. See 518 U.S. at 500-501; Pet. App. 9a.[6] Based on this Court's discussion of the "rigorous" nature of the PMA process, and the Court's comparison between 510(k)-process requirements (which the Court found to be

---

[6] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's painstaking approval of the 4004M device through the PMA process easily satisfies that requirement. See pages 22-24, *infra*.

"important but entirely generic concerns") and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements"; see *Lohr*, 518 U.S. at 501), the vast majority of courts have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 19a-20a; *Brooks*, 236 F.3d at 963-964, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Kemp*, 231 F.3d at 226-27; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

In contrast to the decisions of the Fifth, Sixth, Seventh, and Eighth Circuits, petitioners can identify (at Pet. 14, 16) only one federal court of appeals and one state supreme courts that did not find PMA approval to be preemptive — *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while inconsistent with the decision below, are internally confused and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found parts of the requirements imposed through the PMA process not to be "specific" (167 F.3d at 1376), while acknowledging that other aspects *were* specific (*ibid.*). The FDA's "conditions of approval," barring modification of a device without FDA consent, were specific federal requirements, the court acknowledged, but it found that these were not "'applicable under [the MDA] to the device.'" *Ibid.* (quoting 21 U.S.C. § 360k(a)(1)). This latter holding is not only inconsistent with the former holding but also contrary to *Lohr*, which focused on whether federal requirements were specific or general requirements, not whether they were applicable exclu-

sively to the specific device. See 518 U.S. at 500 ("federal requirements must be 'applicable to the device' in question" under FDA regulations). In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

Weiland, in contrast, found that all aspects of the PMA process were not specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: first, the court held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the device" (*ibid.*) — a statement that, while perhaps true for the device at issue in *Weiland*, certainly was not true in this case, where the FDA repeatedly required modifications of the product or its labeling (see pages 6-9, *supra*); second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153) (emphasis added), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. In light of *Buckman*'s repetition of the significance of PMA review, this decision is plainly incorrect.[7]

---

[7] Petitioners' attempt to conflate the IDE process with the PMA process (see Pet. 16 n.3), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), while the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state

2. On the state side of the *Lohr* preemption equation, petitioners assert that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts have held that such claims can be preempted,[8] a decision that is plainly correct under *Lohr* (see pages 25-26, *infra*). Only one federal court of appeals or state court of last resort (*cf.* S. Ct. R. 10) has relied on a contrary finding to limit the preemptive scope of the MDA — the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (1997). That case is one of the earliest appellate decisions to interpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.[9]

---

requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

[8] See, *e.g.*, Pet. App. 14a-18a; *Kemp*, 213 F.3d at 224; *Brooks*, 236 F.3d at 963, *reh'g en banc granted on other grounds*, 246 F.3d 1149; *Mitchell*, 126 F.3d at 913-914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376-377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117-118.

[9] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements — despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state law duty would "have the effect of establishing a substantive requirement of a specific device" — even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1))). More important, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See page 25, *infra*.[10] This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In four years, there has been no movement by any other court toward the erroneous Oja analysis, and there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*, in light of the overwhelming weight of authority of other courts of appeals and the opinion of the FDA (see page 27 n.13, *infra*) that such state law claims may be preempted.

---

[10] Petitioners' assertion that the Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is based on a quotation taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822. As discussed above (at page 19 n.7), the court also focused on the significant differences between the PMA process and the IDE process.

II. THE DECISION BELOW, FINDING PREEMPTION OF STATE LAW CLAIMS BASED ON THE REQUIREMENTS IMPOSED BY THE PMA PROCESS, IS PLAINLY CORRECT.

The decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur there must be a federal requirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Fifth Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific).

The decision below makes eminent sense. The PMA process imposes a host of specific federal "requirement[s]" on devices such as the Model 4004M lead.[11] We described

---

[11] Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360(e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2),

above (at pages 5-10) the arduous eight-year process that led to the FDA's decision to approve Medtronic's plans to distribute the 4004 and 4004M leads. During that process, "[t]he design of the lead, the labeling on the lead, and the manner of manufacturing of the lead were all submitted to the FDA in great detail and approved by the FDA in the PMA process." Pet. App. 21a; see also *Kemp*, 231 F.3d at 226-27 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913). And most important, approval under the PMA entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both safe and effective." *Lohr*, 518 U.S. at 477, citing 21 U.S.C. § 360e(d)(2). The determination that a product is safe and effective, weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use (21 U.S.C. § 360c(a)(2)(C)), after a process characterized by the Supreme Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 121 S. Ct. at 1018), is of necessity the determination that the details of that device are an appropriate compromise that should not be modified by state law.

360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f)), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), but that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, *the counterpart FDA requirement is established on the date the device can not lawfully be marketed without application for premarket approval.* * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the State. Congress specifically referred to this requirement as one that the FDA should allow to continue *by expressly exempting it* (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45-46. No such exemption would have been thought necessary were the PMA process not a requirement otherwise preemptive of the state law.

2. The Fifth Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device differed from the one required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes pre-empt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504-505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in part). The court below, like *Lohr*, found that state law claims that impose a duty identical to federal requirements would not be preempted. See Pet. App. 21a-22a. But where a state law tort action is based on a requirement that is *not* identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement.

Here, the PMA imposed a specific requirement on Medtronic to make its Model 4004 and Model 4004M leads using the specific design approved, which included using a particular material for the leads' insulation and using the manufacturing processes Medtronic described in its PMA application. By contrast, Texas law requires a plaintiff asserting a design defect to demonstrate an "alternative design," TEX. CIV. PRAC. & REM. CODE § 82.005 (Vernon 1997), see also *Uniroyal Goodrich Tire Co.* v. *Martinez*, 977 S.W.2d 328, 335 & nn. 3, 4 (Tex. 1998) — a design necessarily lacking FDA approval. Moreover, the PMA required Medtronic to use the labeling the FDA approved. Were a jury to impose liability on Medtronic under Texas law for not making the Model 4004M lead with different insulation material, for example,

or for not using different manufacturing processes, that jury would plainly be imposing a different, additional requirement on the lead[12] — and an additional requirement that could itself differ from requirements imposed in other states.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hearing Before the Subcomm. on Oversight and Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review

---

[12] For example, design defect cases in Texas are governed by statutory and common law rules requiring the jury to find that the product as designed is unreasonably dangerous, using a definition that requires balancing risk and utility. 3 COMM. ON PATTERN JURY CHARGES, STATE BAR OF TEX., TEXAS PATTERN JURY CHARGES PJC 71.4B (1998). This is directly parallel to review during the PMA process. Under FDA regulations, the panel reviewing a device for PMA also must weigh "the probable benefit to health from the use of the device" against any risk of injury or illness from its use. 21 C.F.R. § 860.7(b)(3). In order for a panel to conclude that there is the statutorily-required "reasonable assurance that a device is safe," there must be "valid scientific evidence[] that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks." *Id.* § 860.7(d)(1). Thus, were a Texas jury to find the Model 4004 or Model 4004M lead to have a design defect, the jury would have to find that its risks outweigh its benefits, a finding irreconcilable with the finding of the FDA in granting PMA.

and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.[13]

* * * * *

In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of *Buckman* and through further litigation in the lower courts. Petitioners provide no good explanation for why the Court, having just declined to review this very issue in *Kemp*, should grant review in this case, or why the issue deserves the Court's attention at the present time.

CONCLUSION

The petition for a writ of certiorari should be denied.

---

[13] Petitioners purport (at Pet. 20 & n.5) to present evidence of the United States' view on the questions presented herein. The positions taken three years ago in the Solicitor General's brief in *Smith Industries Medical Systems, Inc.* v. *Kernats*, 522 U.S. 1044 (1998) (mem.), were based on the FDA's then-pending proposed rulemaking procedure. See United States Brief in *Kernats*, at 14, 19-20. The FDA has since withdrawn that proposed rule, see Pet. 20-21 n.5, and there is no evidence that those positions reflect the current views of the agency. In any event, petitioners' reliance on the views of the United States is selective. The Solicitor General more recently took the position that "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts * * *." United States Brief in *Buckman*, at 12 n.1.

Respectfully submitted.

RUTH G. MALINAS
Ball & Weed, P.C.
745 E. Mulberry, Ste. 500
San Antonio, Texas 78212
(210) 731-6300

KENNETH S. GELLER
Counsel of Record
DAVID M. GOSSETT
Mayer, Brown & Platt
1909 K Street, NW
Washington, DC 20006
(202) 263-3000

NOVEMBER 2001